REMARKS

No new amendments have been made to claims 1-73. Claims 1-46 and 52-71 have been previously cancelled.

An amendment to the claims was filed on March 11, 2008, adding new claims 74-92. These claims are included here. Support for claims 74-92 may be found though out the specification, and thus now new matter has been added.

Copied Claims

Claims 74-92 have been copied from pending PCT application **WO 2007/130724**, which has designated the United States. These claims correspond as indicated below:

Claim 74 was copied from claim 1 of ***WO 2007/130724.***
Claim 75 was copied from claim 2 of ***WO 2007/130724.***
Claim 76 was copied from claim 3 of ***WO 2007/130724.***
Claim 77 was copied from claim 6 of ***WO 2007/130724.***
Claim 78 was copied from claim 8 of ***WO 2007/130724.***
Claim 79 was copied from claim 9 of ***WO 2007/130724.***
Claim 80 was copied from claim 10 of ***WO 2007/130724.***
Claim 81 was copied from claim 13 of ***WO 2007/130724.***
Claim 82 was copied from claim 15 of ***WO 2007/130724.***
Claim 83 was copied from claim 17 of ***WO 2007/130724.***
Claim 84 was copied from claim 18 of ***WO 2007/130724.***
Claim 85 was copied from claim 29 of ***WO 2007/130724.***
Claim 86 was copied from claim 30 of ***WO 2007/130724.***
Claim 87 was copied from claim 31 of ***WO 2007/130724.***
Claim 88 was copied from claim 32 of ***WO 2007/130724.***
Claim 89 was copied from claim 33 of ***WO 2007/130724.***
Claim 90 was copied from claim 34 of ***WO 2007/130724.***
Claim 91 was copied from claim 35 of ***WO 2007/130724.***
Claim 92 was copied from claim 36 of ***WO 2007/130724.***

35 U.S.C. §103(a) Rejections

Claims 47-51, 72 and 73

Claims 47-51, 72 and 73 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,652,555 Van Tassel et al. ("Van Tassel").

Applicants respectfully disagree.

Van Tassel does not teach or suggest all of the features of the Applicants' claims. Applicants pending claims are method claims directed to methods of treating congestive heart failure by positioning and securing a device *within a patient's ventricular chamber*. Van Tassel does not teach or even suggest this method of treatment. In contrast, Van Tassel teaches a barrier device for coving the opening of an atrial appendage to prevent clots from escaping the atrial appendage.

Although the Office Action of March 3, 2008 acknowledges this difference between Van Tassel and the Applicants' claimed invention, the Office Action asserts that it would be obvious to use the teachings of Van Tassel to achieve the Applicants' claimed methods. This assertion is wrong for at least three reasons. First, the Examiner has not articulated any underlying analysis supporting the assertion of obviousness over Van Tassel. Second, Van Tassel would not achieve the claimed method of treatment and would not function properly if used as suggested by the Examiner. Third, Van Tassel does not teach or suggest all of the steps of the Applicants' method claims, even assuming that Van Tassel operated as asserted by the Examiner. Each of these points is considered in detail below.

(1) The Examiner has not met his prima facie burden to prove obviousness

The Applicants' pending claims are all methods of treating congestive heart failure that require partitioning a subject's ventricular chamber. These claims recite a method including the step of positioning an inflatable partitioning element in the ventricular chamber and engaging the partitioning element with the wall of the ventricular chamber to partition the ventricular chamber into productive and non-productive portions.

In contrast, Van Tassel is directed to devices and methods for covering the opening (ostium) of an atrial appendage (see, e.g., col. 1: 19-21). The devices of Van Tassel are atrial appendage covers that typically include a membrane that can isolate blood clots within the atrial

appendage. Van Tassel teaches that the membrane should be secured over the opening of the atrial appendage (see col. 2: 3-6).

Van Tassel does not teach or suggest a method for treating congestive heart failure. In particular, Van Tassel does not teach or suggest placing these atrial appendage covers within a ventricular chamber, which is dramatically different in both shape, size, location and function compared to an atrial appendage.

In the Office Action of March 3, 2008, the examiner concedes that Van Tassel does not teach a "device that is positioned within a ventricular chamber of a patient's heart" but merely asserts that "[t]he device of the Van Tassel et al reference clearly can be inserted in the ventricular chamber in order to treat the disease." (Office Action of March 3, 2008, page 4). This assertion is unsupported by either the Office Action or by Van Tassel itself.

Applicants respectfully point out that the Examiner's bald assertion that the device of the Van Tassel et al reference "clearly can be inserted in the ventricular chamber in order to treat the disease" does not meet the burden of showing a *prima facie* case of obviousness. As the Supreme Court recently pointed out in *KSR v. Teleflex*, (127 S. Ct. 1727, 1741 (2007)), in order to show obviousness, the Examiner must expressly articulate the underlying analysis supporting the assertion of obviousness over a reference or combination of references ("Rejection of a patent on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support a legal conclusion of obviousness."). As will be described in more detail in part two, below, it is not sufficient that the examiner point to Van Tassel and simply say that Van Tassels devices make the Applicants' methods obvious because they would "yield predictable results." The devices of Van Tassel are concerned with preventing thrombosis, not congestive heart failure, and are configured for use in an atrial appendage, not the ventricle.

In addition to being unsupported, the Examiner's statement that the Applicants' claims are obvious over the devices of Van Tassel because is also incorrect. The devices of Van Tassel would neither work as intended by Van Tassel nor would they perform the claimed methods if they were inserted into the ventricular chamber of the heart as suggested by the Office Action.

(2) The devices of Van Tassel would not work if placed in a ventricle

The Van Tassel device is designed to occlude an opening of an atrial appendage. An atrial appendage is a small cavity shaped liked a small finger or windsock that is connected to the lateral wall of the atrium through a small opening, called the ostium. An atrial appendage may contract modestly during contraction of the atrium in a normal heart, in patients suffering from atrial fibrillation or other disorders the atrial appendage may not contract at all, thereby allowing blood to stagnate (and clots to form) in the atrial appendage (see Van Tassel, col:1: 25-32). The Van Tassel device is therefore designed to cover the atrial appendage, effectively closing it off to prevent blood clots from entering the atrium and then the ventricle. The atrial appendage opening is small (typically 26-30 mm in diameter), and the atrial appendage contracts only a very small amount during the cardiac cycle (typically changing in size only about 6%).

In contrast, the left and right ventricular chambers are the principle pumping chambers of the heart. The diameter of the ventricular chamber is typically much larger than the ostium of an atrial appendage and experiences beat-to-beat diameter changes of 18-19% in diseased hearts and up to 38% in healthy hearts, thereby presenting a much more dynamic environment than the atrial appendage.

The Van Tassel devices, configured to cover the ostium of an atrial appendage, would be unlikely to function within a ventricular chamber, at least because of the vastly different shape and sizes of the ventricular chamber compared to the shapes and sizes of the atrial appendages. Furthermore, the function of the ventricular chamber is dramatically different than the function of the atrial appendage. In particular, the ventricular chamber exhibits a high blood flow rate, and contracts vigorously, particularly compared to atrial appendage.

It is unclear how the atrial appendage covers taught by Van Tassel could be placed within a ventricular chamber with any success. Although the Office Action asserts that the Van Tassel device "clearly can be inserted into the ventricular chamber in order to treat the disease," no support or articulation of the underlying reasoning is provided. Van Tassel itself only describes a device adapted for covering an atrial appendage ostium (or opening), and securing the device over the ostium to prevent blood clots from leaving the atrial appendage. Van Tassel teaches methods that all require placing the membrane of the device over the ostium. The openings of the ventricular chambers are not clearly comparable to the ostium of an atrial appendage for the attachment of the Van Tassel devices.

Indeed, placing the ostium cover devices taught by Van Tassel over any of the openings into the ventricular chambers would likely be harmful if not fatal. The openings into the ventricle include the mitral valve and the aortic valve (for the left ventricle) and the tricuspid valve and the pulmonary valve (for the right ventricle). Placing even the variations of the Van Tassel device having porous membranes over any of these valves would likely catastrophically disrupt the valves and harm, or perhaps kill, the patient.

(3) Van Tassel would not partition the ventricle chamber into productive and non-productive portions, as recited by the Applicants' claims.

Even assuming, *arguendo*, that the devices of Van Tassel could be placed in the ventricle, the Van Tassel devices would not perform the method recited by the Applicants' claims.

Van Tassel does not teach *inflating a partitioning element* so that the peripheral edge of the inflatable partitioning element engages the walls of the ventricle *to partition the camber into productive and non-productive portions*, as recited by the Applicants' claims. Van Tassel does not describe an inflatable partitioning element.

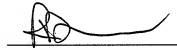
According to Van Tassel, the partitioning element is the membrane (element 40) that spans the opening of the ostium. This membrane (element 40) is not inflatable, and therefore cannot be an inflatable partitioning element, as recited by the claims. The membrane may be held in place by a separate inflatable element (balloon 402) located behind the partitioning membrane (element 40). This balloon element cannot be a partitioning member element as recited by the claims, because it does not partition the chamber (presumably the atrial appendage) into productive and non-productive portions. Instead, as indicated by the Examiner on page 3 of the Office Action in reference to FIG. 18, the regions on either side of the inflated balloon element 402 (the regions behind the membrane 40) are both non-productive regions. The peripheral edge of the balloon element 402 does <u>not</u> engage a wall of the ventricular chamber to partition the chamber into productive and non-productive portions, as recited by all of the pending claims.

Thus, since none of the pending claims are obvious in light of Van Tassel for at least the reasons provided above, the Applicants respectfully request withdrawal of the 35 USC §103(a) rejection of claims 47-51, 72 and 73, and allowance of all of the currently pending claims.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-4050, referencing 10078-703.201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: April 30, 2008 By: 

Richard D. Shoop, Reg. No. 45,763

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562